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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,313	01/14/2005	Joon Youb Lee	Q85741	9295

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EXAMINER
HILL, KEVIN KAI

ART UNIT	PAPER NUMBER
1633	

DATE MAILED: 12/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/521,313	LEE ET AL.	
	Examiner	Art Unit	
	Kevin K. Hill, Ph.D.	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-16* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other:_____.

Election/Restrictions

Group I, Claims 1-16, drawn to a Her2/neu plasmid construct comprising a truncated human Her2/neu gene lacking the intracellular domain, wherein the plasmid further comprises a cytokine gene, a DNA vaccine comprising a first plasmid expressing a truncated Her2/neu gene lacking the intracellular domain and a second plasmid expressing a cytokine gene, and a method for preventing and/or treating cancer, which comprises the step of administering an effective amount of the DNA vaccine.

1. **Should Applicant elect Group I, a species restriction is required under 35 U.S.C. 121 and 372.** This application contains claims directed to more than one species of Her2/neu plasmid constructs. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species listed in Group I do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature for the following reasons:

37 CFR 1.475(c) states:
"If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present."

The common technical feature in the group is a plasmid construct containing a truncated human Her2/neu gene lacking the intracellular domain. This plasmid construct containing a truncated human Her2/neu gene lacking the intracellular domain cannot be a special technical feature under PCT Rule 13.2 because a plasmid construct containing a truncated human Her2/neu gene lacking the intracellular domain is shown in the prior art (Kobayashi et al, Cancer Research 60: 5228-5236, 2000; Bhattacharya et al, Int. Immunopharm. 2(6): 783-796, 2002). Both Kobayashi et al and Bhattacharya et al teach recombinant DNA comprising Her2/neu

intracellular domain (ICD) or extracellular domain (ECD) protein fragments (Kobayashi et al, pg 5232, column 2, lines 18-26; Bhattacharya et al, pg 783, Abstract, lines 6-7) substantially as claimed in Claim 1. Bhattacharya et al teach the use of a nucleic acid encoding a truncate human Her2/neu polypeptide lacking the intracellular domain for a DNA vaccine. Thus, the use of the inventive nucleic acid as a DNA vaccine does not contribute over the prior art.

A search for a plasmid consisting of a human Her-2/neu gene would not be co-extensive with a search for a DNA vaccine consisting of a first plasmid encoding a truncated human Her-2/neu gene and a second plasmid encoding a cytokine. Further, a reference rendering a truncated human Her-2/neu gene having the nucleotide sequence of SEQ ID NO:3 as anticipated or obvious over the prior art would not necessarily also render a DNA vaccine comprising a first plasmid encoding pNeuECD-gDs and a second plasmid encoding IL-18 as anticipated or obvious over the prior art. Because these inventions are distinct for reasons given above, and because a search of one does not necessarily overlap with that of another species, it would be unduly burdensome for the examiner to search and examine all the subject matter being sought in the presently pending claims and thus, restriction for examination purposes as indicated is proper.

In response to the restriction requirement, Applicant must further elect of one of species (a)-(d) below, regarding a patently distinct Her2/neu plasmid constructs consonant with Applicant's elected invention for prosecution on the merits to which the claims shall be restricted, specifically:

a) a Her2/neu plasmid construct, wherein the human Her-2/neu gene has the nucleotide sequence of SEQ ID NO:2, as recited in Claims 2-3,

b) a Her2/neu plasmid construct, wherein the human Her-2/neu gene has the nucleotide sequence of SEQ ID NO:3, as recited in Claims 4-6,

c) a Her2/neu plasmid construct, wherein the signal peptide of the human Her-2/neu gene has been replaced by the signal peptide of herpes simplex type I glycoprotein D (gD), wherein the plasmid construct is pNeuTM-gDs, as recited in Claims 7-8, or

d) a Her2/neu plasmid construct, wherein the signal peptide of the human Her-2/neu gene has been replaced by the signal peptide of herpes simplex type I glycoprotein D (gD), wherein the plasmid construct is pNeuECD-gDs, as recited in Claims 9-10.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the polypeptides lack the same or corresponding special technical features for the following reasons:

The species are drawn to multiple nucleic acids encoding polypeptides that are structurally distinct. Each of the nucleic acids consists of a unique nucleotide sequence, has a distinct melting temperature and a distinct specificity of hybridization. Each of the nucleic acids also encodes for a protein having a distinct amino acid sequence and a distinct biological activity. The numerous variations in the number, position and type of amino acid motifs result in a genus of structurally unrelated molecules that are not obvious variations of each other because one skilled in the art does not expect a Her2/neu polypeptide having the transmembrane domain to have the same functional properties as a Her2/neu polypeptide lacking a transmembrane domain. Furthermore, the HSV type I signal peptide moieties confers a unique, non-obvious, distinctly different technical feature onto the Her2/neu polypeptide that will directly impact the secretion, immunogenicity, and bioavailability or bioactivity of the polypeptide. Each polypeptide possesses a different structure and biases the immune response to distinctly different epitope repertoires available for antigen presentation. Thus, each polypeptide will yield distinctly different effects that are not obvious variations of the others. As the technical feature being a human Her-2/neu polypeptide lacking the intracellular domain linking the members does not constitute a special technical feature as defined by PCT Rule 13.2, the requirement for unity of invention is not fulfilled.

A search for human Her-2/neu gene has the nucleotide sequence of SEQ ID NO:2 would not be co-extensive with a search for plasmid construct is pNeuTM-gDs. Further, a reference rendering human Her-2/neu gene has the nucleotide sequence of SEQ ID NO:3 as anticipated or obvious over the prior art would not necessarily also render pNeuECD-gDs as anticipated or obvious over the prior art. Because these inventions are distinct for reasons given above, and because a search of one does not necessarily overlap with that of another, it would be unduly burdensome for the examiner to search and examine all the subject matter being sought in the presently pending claims and thus, restriction for examination purposes as indicated is proper.

Applicant is required to elect a single named Her2/neu plasmid construct as listed in the cited claims to which the claims shall be restricted. The reply must also identify the claims readable on the elected invention, including any claims subsequently added. Failure to elect a Her2/neu plasmid construct consonant with Applicant's elected Invention may result in a notice of non-responsive amendment. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

The claims are deemed to correspond to the species listed above in the following manner: Claim 1, and claims dependent therefrom correspond to all the species listed above. The following claim(s) are generic: Claims 1 and 13.

Should Applicant elect Group I and a Her2/neu plasmid construct species from (a)-(d) above, a species restriction is required under 35 U.S.C. 121 and 372. This application contains claims directed to more than one species of cytokines. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. In response to the restriction requirement, Applicant must further elect a single cytokine species from the list consisting of the cytokines recited in Claims 12 and 15 consonant with Applicant's elected invention for prosecution on the merits to which the claims shall be restricted.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

The species are drawn to multiple cytokines that are structurally distinct. Each cytokine signals through a distinctly different receptor molecule and stimulates a distinctly different cellular response that are not obvious variations because one of ordinary skill in the art would not expect GM-CSF to stimulate the same biological response as Eta-1 or IL-18. As the technical feature being an immunomodulatory signaling molecule linking the members does not constitute a special technical feature as defined by PCT Rule 13.2, particularly since each of the species

does not share a substantially common structural feature, the requirement for unity of invention is not fulfilled.

A search for GM-CSF would not be co-extensive with a search for IL-15. Further, a reference rendering IL-18 as anticipated or obvious over the prior art would not necessarily also render Eta-1 as anticipated or obvious over the prior art. Similarly, a finding that Flt3L was novel and unobvious over the prior art would not necessarily extend to a finding that IL-12 was also novel and unobvious over the prior art. Because these inventions are distinct for reasons given above, and because a search of one does not necessarily overlap with that of another species, it would be unduly burdensome for the examiner to search and examine all the subject matter being sought in the presently pending claims and thus, restriction for examination purposes as indicated is proper.

Applicant is required to elect a single named cytokine species as listed in the cited claims to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. Failure to elect a cytokine consonant with Applicant's elected Invention may result in a notice of non-responsive amendment. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

The claims are deemed to correspond to the species listed above in the following manner:

Claim 1, and claims dependent therefrom correspond to all the species listed above. The following claim(s) are generic: Claims 11 and 14.

Upon the allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should Applicant traverse on the ground that the species are not patentably distinct, Applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Should Applicant add or amend the claims of the elected invention to introduce subject matter from a non-elected invention for which the above stated group restriction(s) and/or species election(s) is(are) required, then Applicant is required to make the appropriate elections set forth above in accordance with the subject matter recited in the newly added or amended claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin K. Hill, Ph.D. whose telephone number is 571-272-8036. The examiner can normally be reached on Monday through Friday, between 9:00am-6:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph T. Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Kevin K. Hill

Q. JANICE LI, M.D.
PRIMARY EXAMINER